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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KAHELIN, MICHAEL WILLIAM	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/798,919
Filing Date: March 12, 2004
Appellant(s): DONOGHUE ET AL.

MAILED
JUL 26 2007
GROUP 3700

Brad C. Rametta
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/12/2007 appealing from the Office action mailed 5/18/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

20030004428	Pless	1-2003
6,016,449	Fischell et al.	1-2000

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4,974,602

Abraham-Fuchs et al.

12-1990

20030074032

Gliner

4-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim	Limitation	35 USC 102(b) rejection under prior art reference Pless et al. (US 2003/0004428)
1	A system for predicting occurrence of a neurological event in a patient's body	The system is shown schematically in Figure 3 of Pless.
	An implant configured to be placed in the body and detect signals indicative of an activity that precedes the neurological event	The implant is shown as element 110 in Figure 3 of Pless and is disclosed to detect signals indicative of an activity that precedes a neurological event at paragraph 0035.
	A processing unit configured to process the detected signals so as to predict the neurological event prior to the occurrence	The processor is shown as element 428 in Figure 4 and the prediction is described in paragraph 0035.
	A storage device containing a target signal indicative of the activity that precedes the neurological event, the target signal including one or more previously detected signals indicative of the activity that precedes the neurological event	(See Fischell et al. (US 6,016,449), incorporated by reference into Pless at paragraph 0088) The storage device is shown as "Delay parameters" in Fischell's Figure 12 and described at column 24, lines 6-9). Additionally, a threshold "target signal" is disclosed at column 20, lines 19-28.
	Wherein the processing unit is configured to compare the detected signals with the target signal	The comparison for the time delay "target signal" is described at column 23, line 46 through column 24, line 13, and the comparison for the threshold "target signal" is described at column 24, lines 19-28.
64	A method for treating a neurological event in a patient	The method is shown schematically in Figure 3 of Pless.
	Placing an implant in the patient's body	The implant is shown as element 110 in Figure 3 of Pless.
	Detecting signals indicative of an activity that precedes the neurological event	The implant is disclosed to detect signals indicative of an activity that precedes a neurological event at paragraph 0035.

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	Predicting the occurrence of the neurological event based on the detected signals	The processor is shown as element 428 in Figure 4 and the prediction is described in paragraph 0035.
	Wherein predicting includes providing a target signal indicative of the activity that precedes the neurological event, the target signal including one or more previously detected signals indicative of the activity that precedes the neurological event	(See Fischell et al. (US 6,016,449), incorporated by reference into Pless at paragraph 0088) The storage device is shown as "Delay parameters" in Fischell's Figure 12 and described at column 24, lines 6-9). Additionally, a threshold "target signal" is disclosed at column 20, lines 19-28.
	Comparing the detected signals with the target signal	The comparison for the time delay "target signal" is described at column 23, line 46 through column 24, line 13, and the comparison for the threshold "target signal" is described at column 24, lines 19-28.

Claims 1 and 64 are alternatively rejected under 35 USC 103(a) as follows:

Claim	Limitation lacking express, explicit disclosure in Pless	Teaching of element in Abraham-Fuchs et al. (US 4,974,602)	Motivation to modify Pless
1 and 64	The target signal including one or more previously detected signals	The abstract discloses that "templates" are created with measured EEG signals and later compared to continuously measured values to determine "pathologically electrically active" patterns.	Inter-patient variability as taught at column 1, lines 41-52.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59-61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Pless et al. (US 2003/0004428 hereinafter "Pless"). Please note that Fischell et al. (US 6,016,449 hereinafter "Fischell") has been incorporated by reference into the Pless disclosure. Although reference is given to the Fischell reference below, this is only done for Applicant's convenience in referencing the document. Because of the incorporation by reference, **all** listed claims are rejected under the Pless reference only.
2. In regards to claims 1 and 64, Pless discloses an implantable device comprising a means to detect signals indicative of activity preceding an event (422) and a processing unit to predict a neurological event (428 and abstract). Furthermore, the event detection algorithm incorporated by Pless and disclosed by Fischell comprises storing a target signal indicative of activity preceding a neurological event, in the form of a threshold. Examiner is interpreting a threshold as a constant level signal that is inherently set by some previous signal. Additionally, this threshold is compared to detected signals (Fig. 5A-5D) and is indicative of an activity that precedes a neurological event (a "fully-developed" epileptic seizure, see col. 5, line 4).
3. In regards to claims 2 and 65, Pless discloses that the implant is configured to be placed in the patient's brain (224).

4. In regards to claims 3-5 and 66-68, Pless discloses that the implant includes a multi-electrode array (412, 414, 416, and 418) that penetrates into the neural tissue (par. 0080), and are recording and stimulating electrodes (422 and 424).
5. In regards to claims 6 and 69, Pless discloses that at least one electrode detects electrical signals indicative of activity preceding the event (par. 0088).
6. In regards to claims 7 and 70, Pless discloses that the electrode is proximate the implant (224, Fig. 2).
7. In regards to claims 8, 9, 71 and 72, Fischell discloses that the processing unit converts the signals into a recognizable pattern (Fig. 5A-5D) and the pattern includes a formula describing the behavior in time (col. 16, line 43) and space (the 3 electrode traces correspond to 3 points in space).
8. In regards to claims 10 and 73, Fischell discloses that individual neuron signals are isolated from neighboring signals (Fig. 5A-5D). Please note that the Examiner is interpreting "individual neuron signals" as being individual signals corresponding to one or more neurons.
9. In regards to claims 11 and 74, Pless discloses that the signals include spikes (Fig. 9, element 910).
10. In regards to claim 12, Pless discloses that the processor characterizes a pattern of neuronal activity to predict the event (pars. 0088 and 0108).
11. In regards to claims 13 and 75, Pless discloses that the implant is placed proximate the neural focus. Please note that Examiner is interpreting proximate as being close enough to measure the electrical activity.

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12. In regards to claims 14 and 76, Pless discloses that the implant inherently capable of measuring local field potentials, or any other electrical potentials.

13. In regards to claims 15 and 77, Pless discloses that the implant detects EcoG signals (par. 0013).

14. In regards to claims 20, 21, 82 and 83, Fischell discloses that the implant comprises a subdural grid with a multi-electrode array (col. 2, line 59).

15. In regards to claims 26-28, 58, 88-90, 119, and 120, Fischell discloses that signals preceding a neurological event are characterized, stored, and compared to detected signals. Additionally, the target signal is modified over time adaptively (col. 16, line 54 through col. 17).

16. In regards to claims 29-32 and 91-93, Pless discloses that the device comprises a recording device (426), detects biological signals (abstract), comprises a sensor to detect other signals and communicates with the processor (par. 0112), and compares the signals detected by the implant with the other signals (par. 0112).

17. In regards to claims 33 and 94, Pless discloses that the processor differentiates activity preceding the event from normal activities (par. 0035).

18. In regards to claims 34-38, Fischell discloses that the processor outputs information related to the patient's condition (col. 7, line 43), including an indicator, which is an external device (11) that has a visual indicator (80).

19. In regards to claims 39 and 95-99, Fischell discloses an output device that is external, displays information, and includes a warning signal (col. 7, line 58).

20. In regards to claims 48-50 and 108-111, Fischell discloses that the processor generates a control signal to suppress the event with electrical current to the central nervous system (col. 2, line 52).

21. In regards to claims 54 and 115, Fischell discloses that the impedance is reduced between electrodes (col. 4, line 43).

22. In regards to claims 59, 61 and 122, Fischell discloses that the event is an epileptic symptom, which is inherently undesired (abstract).

23. In regards to claim 60, the implant is located at an epileptic focus (col. 27, line 62).

24. In regards to claim 63, Pless discloses that "readiness potential" is measured because his device measures how ready the brain is to have a seizure.

25. In regards to claims 105 and 106, Fischell discloses causing movement of a portion of the patient's body comprising a stimulating signal (col. 7, line 63). Please note that the movement is vibration and is inherently felt by the patient.

26. In regards to claim 121, Fischell discloses determining whether an event occurred, whether it was mistakenly predicted, and modifying the target signal based on whether the event was mistakenly predicted (col. 19).

27. In regards to claim 123, Fischell discloses that the implant is proximate the epileptic focus (col. 3, line 4).

28. In regards to claims 124-126, Fischell discloses that the signals are preprocessed, comprising calibrating detected signals based on background signals (col. 15, line 1), and includes filtering (col. 14, line 63).

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

31. Alternatively, claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in view of Abraham-Fuchs et al. (US 4,974,602, hereinafter "Abraham-Fuchs"). Pless discloses the essential features of the claimed invention except for explicitly specifying that the target signals be previously detected. Abraham-Fuchs teaches of providing a system for recognizing neurological events by comparing a detected signal to a previously detected template signal indicative of activity preceding a neurological event (abstract) to allow recognition of pathologies with high patient-to-

patient variability (col. 1, line 41). Therefore, it would have been obvious to provide Pless' invention by comparing a detected signal to a previously detected template signal indicative of activity preceding a neurological event to allow recognition of pathologies with high patient-to-patient variability.

32. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pless or Pless in view of Abraham-Fuchs. Pless (or Pless in view of Abraham-Fuchs) discloses the essential features of the claimed invention except for explicitly indicating that movement is caused to a finger of a patient. Pless does disclose applying stimulation to the median nerve (col. 7, line 62). Further, it is well known in the art to apply a suprathreshold stimulation to nerves to cause movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Pless (or Pless in view of Abraham-Fuchs) by providing a suprathreshold stimulation to the median nerve to induce movement of a finger to indicate impending seizure.

33. Claims 22 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless (or Pless in view of Abraham-Fuchs) in view of Gliner (US 2003/0074032 hereinafter "Gliner"). Pless (or Pless in view of Abraham-Fuchs) discloses the essential features of the claimed invention except for providing a movement sensor to detect movement of the brain. Gliner teaches of providing a movement sensor (par. 0036) to more accurately detect seizure activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Pless' (or

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Pless in view of Abraham-Fuchs) invention with a movement sensor to more accurately detect seizure activity.

(10) Response to Argument

The section 102(b) rejection of claims 1 and 64 based on Pless should be reversed because:

1. Pless/Fischell discloses comparing signals with a threshold described only as preset to minimize missing real events

Appellant argued that the threshold disclosed by Fischell is fixed and not a previously detected signal indicative of activity that precedes a neurological event, but is only programmed to minimize the chance of missing a "real" neurological event, such as disclosed at column 17, lines 9-12 and column 20, lines 19-28. The Examiner takes the position that, although the threshold disclosed by Fischell is preset, it is preset based "previously detected signals" because the rate of false positives disclosed at column 20, line 27, is not an arbitrary value, but set to a specific value of $\frac{1}{2}$ to 5 times as many false positives to "real" events. To arrive at this set rate of false positives for a given patient, the threshold that provides this set value must first be determined, or "previously detected".

Additionally or alternatively, as described in the previous Office communication (see "Advisory Action" of 5/18//2006, paragraph 1), Fischell further discloses at column 24, line 6, that a time delay "target signal" is stored, is indicative of activity that precedes a neurological event, and is previously detected (during diagnostic testing).

2. Pless/Fischell does not expressly or inherently disclose a target signal that includes a “previously detected signal”

Appellant argued that Pless/Fischell is lacking explicit or inherent disclosure of a “previously detected signal”. Appellant further gave examples to refute the position that the threshold disclosed by Fischell is inherently “previously detected” including providing an arbitrarily low value to ensure a sufficient number of false positives or selecting data based on seizure-free subjects. However, as described above, an arbitrary threshold cannot be used because the rate of false positives is disclosed as being a set value. Providing a non-arbitrary rate of false positives requires a non-arbitrary threshold. Additionally, pre-selecting a threshold based on seizure-free human or non-human primate test subjects would not violate the limitation that the signal be “previously detected signals indicative of the activity that precedes the neurological event”. As such, the Examiner maintains the position that the set rate of false positives requires “previously detected signals”.

The section 103(a) rejection of claims 1 and 64 based on Pless and Abraham-Fuchs should be reversed because:

1. The examiner admits that Pless does not teach the claimed invention

Although the Examiner stated in the March 28, 2006 Office Action that, “Pless discloses the essential features of the claimed invention except for explicitly specifying that the target signal be previously detected”, the Examiner maintains the inherency argument detailed above.

2. The Abraham-Fuchs "template" does not include a previously detected signal indicating activity preceding an event

Appellant argued that Abraham-Fuchs' signal does not constitute a signal indicative of the activity that precedes a neurological event, but is merely data collected from earlier in time. Pless is relied upon for the teaching of predicting a neurological event, such as seizure, by comparing a signal indicative of the activity that precedes a neurological event. Abraham-Fuchs was relied on merely for the ubiquitous teaching of using previously detected patient-specific baseline data for a basis of comparison. It is notorious in the medical arts to diagnose conditions by determining the similarity of parameters to previously measured parameters that indicate said conditions. Abraham-Fuchs is one of many examples of this principle.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael Kahelin

MK MK 7/23/07

Conferees:

[Signature]
Janet Baxter

[Signature]
Angela Sykes